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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,151	08/24/2001	Hirofumi Hamada	766.56	1764

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NEW YORK, NY 10112

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

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DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,151

Applicant(s)

HAMADA, HIROFUMI

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1 claim(s) 4 -20, drawn to virus vectors comprising a virus structural protein fused with a ligand that binds to a melanocyte-stimulating hormone (MSH) receptor, wherein the structural protein is fused to the ligand via a linker having the amino acid sequence of SEQ ID NO:25.

Group 2 claim(s) 4-20, drawn to virus vectors comprising a virus structural protein fused with a ligand that binds to a melanocyte-stimulating hormone (MSH) receptor, wherein the structural protein is fused to the ligand via a linker having the amino acid sequence of SEQ ID NO:27.

Group 3 claim(s) 4-20, drawn to virus vectors comprising a virus structural protein fused with a ligand that binds to a melanocyte-stimulating hormone (MSH) receptor, wherein the structural protein is fused to the ligand via a linker having the amino acid sequence of SEQ ID NO:29.

Group 4 claim(s) 4-20, drawn to virus vectors comprising a virus structural protein fused with a ligand that binds to a melanocyte-stimulating hormone (MSH) receptor, wherein the structural protein is fused to the ligand via a linker having the amino acid sequence of SEQ ID NO:31.

Group 5, claim(s) 21 and 24, drawn to proteins comprising the amino acid sequence of SEQ ID NOS: 32 or 33.

Group 6, claim(s) 21 and 24, drawn to proteins comprising the amino acid sequence of SEQ ID NOS: 34 or 35.

Group 7, claim(s) 21 and 24, drawn to proteins comprising the amino acid sequence of SEQ ID NOS: 36 or 37.

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Group 8, claim(s) 21 and 24, drawn to proteins comprising the amino acid sequence of SEQ ID NOS: 38 or 39.

Group 9, claim(s) 22, 23, 25, and 26, drawn to DNA encoding the amino acid sequence SEQ ID NOS: 32 or 33.

Group 10, claim(s) 22, 23, 25, and 26, drawn to DNA encoding the amino acid sequence SEQ ID NOS: 34 or 35.

Group 11, claim(s) 22, 23, 25, and 26, drawn to DNA encoding the amino acid sequence SEQ ID NOS: 36 or 37.

Group 12, claim(s) 22, 23, 25, and 26, drawn to DNA encoding the amino acid sequence SEQ ID NOS: 38 or 39.

Claims 1-3 link(s) inventions 1-4. Claim 5, which depends from any one of claims 1-4, also links inventions 1-4 to the extent that it depends from claims 1, 2, or 3. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If any one of groups 1-4 is elected, a further restriction requirement is made between the inventions of antitumor agents and diagnostic agents. Applicant is advised that this is a restriction between inventions and not an election of species. Generic claims will be examined to their full breadth in order to make a patentability determination. Claims 1-18 are generic to the antitumor agent invention, and claims 1-9, 19, and 20 are generic to the diagnostic agent invention.

The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There can be no special technical feature linking the inventions because claim 1 is anticipated by the prior art. Specifically, Spooner et al (WO 94/10323, 5/11/94) teach an adenovirus with a penton fiber protein comprising a binding moiety that recognizes an MSH receptor. See abstract; paragraph bridging pages 4 and 5; page 5, lines 9 and 10; page 6, lines 10-16; page 9, lines 13 and 14; page 10, lines 13-15; page 13, lines 4-7, and 22-26; and claims 9, 11, 22, and 23. Because independent claim 1 is anticipated by the prior art, there can be no special technical feature that links the various inventions, and unity of invention is lacking. Further, SEQ ID NOS: 25, 27, 29, and 31 lack unity of invention because they represent separate and distinct amino acid sequences. These sequences do not have any single common structural element as set forth in the Administrative Instructions Under the PCT, see annex B, under "Markush Practice", so restriction between them is proper. Similarly, restriction between viral vectors, DNAs encoding proteins, and proteins is proper because while 37 CFR 1.475 allows for grouping

together of different categories of invention (i.e. compositions, methods of making compositions, and methods of using compositions) so long as a unifying special technical feature is present, it does not allow for grouping together of different types of compositions as a single invention.

Election of Species

This application contains claims directed to more than one species of the generic invention. Should applicant elect any one of groups 1-4 a further election of species is required based on the virus family from which the virus vector is selected. Applicant is required to elect one of the following inventions: *Adenoviridae*, *Retroviridae*, *Parvoviridae*, *Herpesviridae*, *Poxviridae*, *Papovaviridae*, *Hepadnaviridae*, *Togaviridae*, *Flaviviridae*, *Coronaviridae*, *Rhabdoviridae*, *Paramyxoviridae*, *Orthomyxoviridae*, *Bunyaviridae*, *Arenaviridae*, and *Reoviridae*. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1, for the reasons given above, i.e. the prior art anticipates one of the species (*Adenoviridae*) so there can be no special technical feature linking the various species. See Spooner et al (WO 94/10323, 5/11/94), as discussed above. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the


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hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER